

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products) MD 15-02641-PHX-DGC
Liability Litigation,)
)
)
Lisa Hyde and Mark Hyde, a married) Phoenix, Arizona
couple,) September 25, 2018
)
)
Plaintiffs,)
)
)
v.) CV 16-00893-PHX-DGC
)
)
C.R. Bard, Inc., a New Jersey)
corporation, and Bard Peripheral)
Vascular, an Arizona corporation,)
)
)
Defendants.)
)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 6 - P.M. SESSION

Official Court Reporter:
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC
Sandra Day O'Connor U.S. Courthouse, Suite 312
401 West Washington Street, Spc 42
Phoenix, Arizona 85003-2151
(602) 322-7198

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

A P P E A R A N C E S

For the Plaintiffs:

Lopez McHugh
By: **RAMON R. LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Gallagher & Kennedy
By: **MARK S. O'CONNOR, ESQ.**
PAUL L. STOLLER, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Heaviside Reed Zaic
By: **JULIA REED ZAIC, ESQ.**
 LAURA E. SMITH, ESQ.
312 Broadway, Suite 203
Laguna Beach, CA 92651

Goldenberg Law PLLC
By: **STUART GOLDENBERG, ESQ.**
MARLENE GOLDENBERG, ESQ.,
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402

Lopez McHugh, LLP
By: **JOSHUA MANKOFF**, ESQ.
1 International Plaza, #550
PMB-059
Philadelphia, PA 19113

1 A P P E A R A N C E S (CONTINUED)

2 For the Defendants:

3 Nelson Mullins Riley & Scarborough
4 By: **JAMES F. ROGERS**, ESQ.
5 1320 Main Street
6 Columbia, SC 292017 Snell & Wilmer
8 By: **JAMES R. CONDO**, ESQ.
9 400 East Van Buren
10 Phoenix, AZ 8500411 Nelson Mullins Riley & Scarborough
12 By: **RICHARD B. NORTH, JR.**, ESQ.
13 **MATTHEW B. LERNER**, ESQ.
14 **ELIZABETH C. HELM**, ESQ.
15 201 17th Street NW, Suite 1700
16 Atlanta, GA 3036317 C.R. Bard, Inc.
18 Associate General Counsel, Litigation
19 By: **GREG A. DADIKA**, ESQ.
20 730 Central Avenue
21 Murray Hill, New Jersey 07974

INDEX OF EXHIBITS (Continued)

<u>EXHIBIT</u>	<u>RECEIVED</u>
<u>NO.</u>	<u>DESCRIPTION</u>
1680	McDonald Deposition, 07/29/2016 - Exhibit 21 - 7/13/2015 Warning Letter from the FDA regarding the 11/25/2014 Inspection of the C.R. Bard facility in NY and the 11/18/2014-1/5/2015 Inspection of the BPV facility in AZ (Redacted) 1355
4515	Monthly Management Report, dated 4/8/10 Pages 12 and 13 only 1364
2057	Sullivan, 11/03/2016, Exhibit 442 - Recovery Filter Migration Remedial Action Plan SPA-04-12-01 dated 1/4/2005, including the Lehmann Report and Dr. Ciavarella's 12/17/2004 HHE titled "Recovery Filter - Consultant's report" 1371
1216	Ganser Deposition, 10/11/2016 - Exhibit 526 - Regulatory Affairs Manual Re. "Product Remedial Actions", RA-STD-002 Rev. 08, dated 10/12/2000 1371
922	Ciavarella Deposition, 11/12/2013 - Exhibit 22 - Chart of Sales and Adverse Events for all competitors from Q3/00 through Q2/03, according to the MAUDE database. 1371
923	Ciavarella Deposition, 11/12/2013 - Exhibit 24 - Summary of Sales and Adverse Events for all competitors from 01/00 through Q1/04 1371
924	Ciavarella Deposition, 11/12/2013 - Exhibit 26 - Chart of Sales and Adverse Events for all competitors from 01/00 through Q1 2006, according to the MAUDE database. 1371
925	Ciavarella Deposition, 11/12/2013 - Exhibit 28 - PowerPoint presentation entitled "Filters Complaint History Data as of 7/31/2007" by Natalie Wong 1371

INDEX OF EXHIBITS (Continued)

	<u>EXHIBIT</u>	<u>RECEIVED</u>	
	<u>NO.</u>	<u>DESCRIPTION</u>	
4	991	Cortelezzi, 11/11/2016, Exhibit 586 - 12/23/2005 E-mail from David Ciavarella Re. "G2 Caudal Migrations", forwarded to Brian Barry on 12/27. Worst case consequence of migrations - accompanied in a majority of tilt cases. Would like to now look at G2 complaints.	1371
7	927	Ciavarella Deposition, 11/12/2013 - Exhibit 35 - Health Hazard Evaluation Memo from Ciavarella to Uelmen Re. "Recovery Filter - Consultant's report", dated 12/17/2004	1371
10	931	Ciavarella Deposition, 11/12/2013 - Exhibit 39 - Draft of Updated Health Hazard Evaluation Memo from Ciavarella to Uelmen, Re: "Limb Fractures of Recovery Filter", dated 7/9/2004.	1371
13	1221	Ganser Deposition, 10/11/2016 - Exhibit 533 - 2/15/2006 Health Hazard Evaluation from David Ciavarella to Gin Schulz Re. "G2 Inferior Vena Cava Filter - Migration" (Redacted)	1371
15	1578	Kessler Report ETR-06-28-29, revision 0, project #8049, Caudal Migration Test Method Development and G2 Filter Resistance Test Report, 11/27/06	1377
18	4409	G2 brochure 2	1383
19	4438	G2 Express Vena Cava Filter Brochure	1386
20	4430	Eclipse Vena Cava Filter Brochure	1388
21	1616	Little Deposition, 06/27/2016 - Exhibit 2003 - "Patient Questions & Answers" Brochure for the G2 Filter System	1390
23	770	Carr Deposition, 12/19/2013 - Exhibit 06 - Bard's Denali Concept Product Opportunity Appraisal, POA-8108, Rev. 1.0	1392
25	504	Eclipse Concept POA	1398

INDEX OF EXHIBITS (Continued)

<u>EXHIBIT</u>	<u>RECEIVED</u>
<u>NO.</u>	<u>DESCRIPTION</u>
769	Carr Deposition, 12/19/2013 - Exhibit 05 - BPV Meridian Claims Matrix, dated 7/2/2010 1401
4785	Fermanich Deposition, 3/17/17 - Exhibit 2: Email, from Tim Hug, 3/19/10, Re: Adversity-How are you going to respond (6 pages) 1406
4786	Fermanich Deposition, 3/17/17 - Exhibit 3: Email, from Tim Hug, 4/27/10, Re: Flair-April Expected Results (3 pages) 1406
4794	Fermanich Deposition, 3/17/17 - Exhibit 11: Email from Tim Hug to Hans Yentz (and others), 2/9/10, Subject: Filter Accounts-Eclipse Transition (2 pages) 1406
4795	Fermanich Deposition, 3/17/17 - Exhibit 12: G2 Filter product brochure (4 pages) 1406
4797	Fermanich Deposition, 3/17/17 - Exhibit 14: Email from Tim Hug to Nine Aghakhan (and others), 3/24/10, Subject: FW: G2 X not available for order (2 pages) 1406
4798	Fermanich Deposition, 3/17/17 - Exhibit 15: Email from Bret Baird to TPW-PV Sales-DG, 4/28/10, Subject: When was the last time... (2 pages) 1406
4809	Fermanich Deposition, 3/17/17 - Exhibit 26: Email from Tim Hug to Matt Fermanich, 12/13/00, Subject: G2 Filter Discontinued (2 pages) 1406
4812	Fermanich Deposition, 3/17/17 - Exhibit 29: BPV Memo from Filter Marketing to Bill Little, 4/27/10, Subject: Filter naming (2 pages) 1406

PROCEEDINGS

(Jury not present.)

(Proceedings resumed at 12:55 p.m.)

MS. HELM: Your Honor, may I correct a misstatement I made on the record?

THE COURT: Yes.

MS. HELM: During the sidebar, I said that you had not admitted any complaint files. And actually, when I went back and looked, at least Exhibit 3270 is a complaint file that was admitted in Jones, so I wanted to correct my error. And for the record, it was my mistake.

THE COURT: All right. Well, that was a complaint record detail report that I said was admissible.

MS. HELM: Yes, Your Honor. You admitted Exhibit 3270 in Jones, and so my statement that you had not admitted a complaint record detail report was in error, and I wanted to correct that for the record.

THE COURT: All right. Well, I went back over the lunch hour and reread the orders at Dockets 11122, 11157, and 11256. I think those orders should govern the same evidence in this case. If you want me to depart from those, we should have specific reasons, but that was after lots of litigation and briefing and cases where I worked that out.

Let me give you the ruling on the deposition excerpts that are coming up. I was given, at the beginning of the lunch

1 hour, Exhibit 4804. That's one where yesterday I admitted the
2 statement by Mr. Fermanich, F-E-R-M-A-N-I-C-H, on February 16th
3 as an admission of a party opponent. I did not admit the email
4 he received from Mary Starr before that and to which he was
5 responding or the email afterward that Ms. Starr sent that
6 doesn't appear to have any response.

7 The arguments that have been made with respect to
8 admitting those two statements by Ms. Starr are, this morning
9 it was argued that they're present sense impressions. I do not
10 believe they are present sense impressions within the meaning
11 of Rule 803(1). They are not a description of an event the
12 declarant is perceiving made while the declarant is perceiving
13 it. There's no evidence that Starr personally perceived this
14 information or made a contemporaneous declaration.

15 It's also been argued that -- yesterday that they are
16 adopted admissions. I cannot see any adoption of the
17 statements by Bard, for example, as it does in some of its
18 internal reports with complaint files.

19 And the last argument is that it goes to notice.
20 That's another way of saying it's not admitted for the truth of
21 the matter asserted. That's clearly not correct as to the
22 second email from Ms. Starr, the February 17th one, where she
23 says, "We still have a G2 in stock." I think it's being
24 admitted to show they had a G2 in stock, which is the truth of
25 the matter asserted.

1 However, when I look at the February 16th memo from
2 Ms. Starr to Mr. Fermanich, that doesn't appear to me there's
3 any truth of a matter asserted. It's a question she asks,
4 which is: I need to order some filters. Is it the Eclipse or
5 the G2?

6 There's no assertion there. I think that question is
7 necessary to understand Mr. Fermanich's response to the
8 question. So I am going to admit the first email from
9 Ms. Starr in Exhibit 4804 but not the second one, to which
10 there was no response about the fact that they had a G2 in
11 stock.

12 In light of that ruling, I'm going to sustain the
13 objection to page 202, lines 17 through 22 of the Fermanich
14 deposition, so those should not be played. But I'm going to
15 overrule the objection to page 203, lines 9 through 12, because
16 that's where it's just testimony about the question.

17 So that's my ruling on the deposition exhibits and on
18 Exhibit 4804.

19 (Exhibit No. 4804 was partially admitted into
20 evidence.)

21 THE COURT: And with that, we'll bring the jury in.

22 MR. O'CONNOR: Your Honor, on these complaints, I'm
23 going to go through three of them that I asked about in Jones.
24 I'm going to move for their admission. And then I'm going to
25 show him a monthly report that I showed in Jones to get him to

1 commit that the summary is the same type of summary he sees in
2 the complaints. And I don't think there should be any other
3 objections. I'm going to move for those to be admitted,
4 subject to anything that we have to remove from these complaint
5 files.

6 THE COURT: Ms. Helm?

7 MS. HELM: Your Honor, I'm aware that 3270 was
8 admitted in Jones, and I'm not -- Mr. O'Connor hasn't told me
9 what the other two are. In our tracking, we don't show that
10 any of the others were actually admitted, so I'm happy to look
11 at them.

12 THE COURT: Well, I will tell you, and my memory is,
13 that when I wrote Exhibit 11122 and I said that the chart was
14 based on internal complaint record detail reports such as
15 Exhibit 3270, my memory was that Mr. O'Connor had showed him
16 two or three of those reports. And I said those would be
17 admissible, along with the one monthly management report.

18 So -- and then later I concluded that it was
19 reasonable to introduce those as illustrative of kinds of
20 complaint record detail reports, and I overruled the hearsay
21 objection for two different reasons. I overruled the 403
22 objection in light of the limited evidence that was coming in.

23 So I guess I'm not understanding, Ms. Helm, why you
24 would object to three of those coming in.

25 MS. HELM: If it's three, and it's the three that he

1 used in Jones as redacted in Jones and he can give me those
2 numbers, I think we're fine, Your Honor, and the same monthly
3 management report as redacted in Jones.

4 THE COURT: And they'll be subject to redaction later.
5 I assume you're not going to put the whole report up in front
6 of the jury.

7 MS. HELM: They should already be redacted.

8 MS. REED ZAIC: I believe they are already redacted
9 from Jones. I will verify with --

10 MR. O'CONNOR: Let me just make sure, because I really
11 don't want to draw objections. I shouldn't have drawn that one
12 before. 3262, 3270, and 3304.

13 And, Your Honor, I would ask that counsel be careful
14 before they stop our testimony from now on, unless they're
15 positive you've made a ruling, so we don't get sidetracked.

16 THE COURT: I don't understand what you're saying,
17 Mr. O'Connor.

18 MR. O'CONNOR: She said that you didn't admit these
19 earlier and you did, two of them at least.

20 THE COURT: Well, we've all been wrong on our
21 objections sometimes.

22 MR. O'CONNOR: Fair enough. I'm just trying to keep
23 things moving.

24 MS. HELM: And for the record, Your Honor, I simply
25 made an objection. I stated the rules, and you called us up.

1 THE COURT: Well, at sidebar you said I didn't admit
2 it. The objection was 801, 802, 403, 402, and we had to have a
3 sidebar to address those.

4 MR. O'CONNOR: And then the monthly management report
5 is 4515.

6 THE COURT: And that's the one that was used before
7 with Modra.

8 Okay. Let's bring the jury in.

9 By the way, counsel, I have a criminal sentencing at
10 4:30 today, so we'll need to break and clean up fairly quickly,
11 if we can, so we -- the defendant is in custody, and it's going
12 to hold up the bus downstairs if we take too long to get him
13 sentenced. So we'll try to transition to that fairly quickly.
14 But I'd still like to go to 4:30 to get as much trial time as
15 we can in today.

16 MR. O'CONNOR: Sure. Thank you.

17 (Jury present.)

18 THE COURT: Do we have Mr. Modra back in here?

19 Oh, you are. Mr. Modra, you can come right up after
20 the jury is seated and have a seat.

21 THE WITNESS: Thank you.

22 THE COURT: Please be seated.

23 All right, ladies and gentlemen. We are going to
24 continue with the testimony of Mr. Modra.

25 Mr. O'Connor, you may proceed.

1 MR. O'CONNOR: Yes.

2 Felice, can you show Exhibit 3262, please. And would
3 you go to page 2, Felice.

4 MR. LOPEZ: Page 3?

5 MR. O'CONNOR: Sorry?

6 MR. LOPEZ: Page 3?

7 MR. O'CONNOR: Page 2.

8 CHAD MODRA,

9 called as a witness herein by the plaintiffs, having been
10 previously duly sworn or affirmed, resumed the stand and
11 continued to testify as follows:

12 DIRECT EXAMINATION (Continued)

13 BY MR. O'CONNOR:

14 Q. All right. Mr. Modra, this is a complaint record detail
15 report that is completed by the persons who are assigned to do
16 the investigations and complete the reports accurately and
17 thoroughly; correct?

18 A. It is a complaint record detail report, that's correct.

19 Q. And if we go to, please, page 3.

20 And as we see the Contact Log on 3/10/10, do you see
21 the date up at the top?

22 A. I do.

23 Q. And it says it was reported by a company rep. Do you see
24 that?

25 A. Yes.

1 Q. And that is the type of information that you -- that Bard
2 requires the employees and people responsible for these
3 complaint reports to collect and put in these reports; true?

4 A. It's the narrative, correct.

5 MR. O'CONNOR: And then also, if we go to page 5,
6 please, Felice.

7 BY MR. O'CONNOR:

8 Q. Here's another section of the complaint record detail
9 report. And again, it starts out, "It is reported" at the top.

10 Do you see that?

11 A. "It was reported," yes.

12 Q. And that's typical of the information that's collected by
13 Bard and the people responsible for generating these complaint
14 files; true?

15 A. It typically starts with those words, that's correct.

16 Q. And what happens is that you use summaries such as what
17 we're looking at for other documents, including monthly
18 management reports that we've discussed before; true?

19 A. Summaries as well as product failure codes, other analyses.

20 MR. O'CONNOR: And move to admit Exhibit 3262, Your
21 Honor.

22 MS. HELM: No objection, Your Honor, subject to your
23 prior ruling.

24 THE COURT: Admitted.

25 (Exhibit No. 3262 admitted into evidence.)

1 BY MR. O'CONNOR:

2 Q. And, Mr. Modra, just specifically --

3 MR. O'CONNOR: Publish to the jury, please.

4 THE COURT: You may.

5 MR. O'CONNOR: And if we go to page 3, Felice.

6 BY MR. O'CONNOR:

7 Q. And as we look at this --

8 MR. O'CONNOR: May we publish to the jury, Your Honor?

9 THE COURT: It's published.

10 MR. O'CONNOR: Thank you.

11 BY MR. O'CONNOR:

12 Q. This complaint report has to do with the G2, is that
13 correct, G2 filter?

14 MR. O'CONNOR: Felice, why don't you go ahead, and
15 I'll show Mr. Modra where I found G2.

16 If you could enlarge the complaint that we're looking
17 at under Contact Log, please, Felice.

18 BY MR. O'CONNOR:

19 Q. Mr. Modra, this talks about a detached filter limb.

20 Do you see that at the top?

21 A. Filter limbs.

22 Q. Detached limb remained in the patient.

23 Do you see where I'm reading?

24 A. Yes.

25 MR. O'CONNOR: Felice, can you highlight that first

1 paragraph in Contact Log?

2 THE WITNESS: Yeah, I see that.

3 BY MR. O'CONNOR:

4 Q. And it was a detached limb. When you talk about detached
5 limb, you're talking about a fracture; correct?

6 A. It's also known as that, correct.

7 Q. Thank you.

8 MR. O'CONNOR: And if we go to page 12, Felice. And
9 go to the Conclusion and highlight the Conclusion.

10 BY MR. O'CONNOR:

11 Q. As we discussed earlier, Mr. Modra, part of the complaint
12 investigation should be to take steps to do a root cause
13 analysis?

14 A. That's correct.

15 Q. And here, the complaint investigation confirmed a broken
16 foot and an arm; correct?

17 A. That's correct.

18 Q. And we saw where a detached limb went into the patient's
19 lung before. Do you recall that earlier in the report, we
20 talked about that?

21 A. I didn't see exactly where it was reported to.

22 Q. We can go back.

23 But here's the point: A definitive root cause is
24 unknown.

25 Did I read that correctly?

1 A. That's correct.

2 Q. But what you did see earlier was that it was a detached
3 limb; is that correct?

4 A. Yes.

5 MR. O'CONNOR: And, Felice, if you go to page 5.

6 I'm sorry. I said the wrong thing to you.

7 The top paragraph, Felice, if you would highlight that
8 and enlarge that for Mr. Modra.

9 BY MR. O'CONNOR:

10 Q. And in this case, a detached limb went to the pulmonary
11 artery.

12 Do you see that?

13 A. Yes, I do.

14 Q. And there was no attempt to remove the limb, and it
15 remained in place.

16 Did I read that correctly?

17 A. Yes.

18 MR. O'CONNOR: And, Felice, if you would go to page 3.

19 And just if we look down, Mr. Modra, at --

20 Felice, do you see where it says, "Bard G2 filter
21 system"? And enlarge that.

22 BY MR. O'CONNOR:

23 Q. Exhibit 3262 is a complaint that dealt with a Bard G2
24 filter; is that correct?

25 A. That's correct.

1 Q. And it's a filter that fractured, and the limb went into
2 this patient's pulmonary artery; correct?

3 A. Correct.

4 Q. And this is an example of how complaints are handled at
5 Bard; correct?

6 A. They're handled in this manner. An investigation is
7 conducted.

8 Q. And if Bard wanted to find out how many G2 fracture reports
9 it had received where the filter limb or arm had detached and
10 gone to the heart, the pulmonary artery, or anywhere else in a
11 patient's body, you have the ability to do that at Bard; true?

12 A. As long as it was reported to us or we were able to get
13 that information from the complainant, correct.

14 Q. When it goes into the complaint, it should be obtainable by
15 people like you for purposes of tracking and trending; fair?

16 A. Correct.

17 Q. And, also, if FDA wanted to know how you were taking and
18 reporting complaints, you certainly have to make that
19 information available to FDA if they come to Bard; is that
20 fair?

21 A. Of course.

22 MR. O'CONNOR: All right. Felice, next one I'd like
23 to show is 3270. And go to page 2 -- oh, number 1, just
24 staying at page 1.

1 BY MR. O'CONNOR:

2 Q. You agree that this is another complaint record detail
3 report by Bard with information that's gathered in the
4 regulatory requirements and the ordinary course of Bard's
5 business?

6 A. Yes.

7 MR. O'CONNOR: Move to admit 3270.

8 MS. HELM: No objection subject to your prior order.

9 THE COURT: Admitted.

10 (Exhibit No. 3270 admitted into evidence.)

11 BY MR. O'CONNOR:

12 Q. And for purposes of the jury, if -- Mr. Modra, if we go to
13 page 2 --

14 MR. O'CONNOR: And, Felice, if you could pull out that
15 top paragraph, please.

16 May I publish, Your Honor?

17 THE COURT: You may.

18 BY MR. O'CONNOR:

19 Q. And, Mr. Modra, this was reported to Bard on March 30,
20 2010?

21 A. That's correct.

22 Q. And as you can see, it's a G2 filter. If you look down,
23 the third line up, it says G2 filter.

24 A. That just says the subject of the email. I don't know if
25 they -- we actually subsequently found that to be the case.

1 That's why I was looking for the other references.

2 Q. Well, we'll go down lower and I'll show you where they
3 listed product name.

4 You would expect whoever generated this report to be
5 accurate; correct?

6 A. Based on the information at the time, they may have
7 believed it to be a G2 filter. That's why we always try to
8 confirm it.

9 Q. Here's what was reported to Bard: A filter limb
10 detached -- in other words, broke -- and was found in the
11 patient's heart.

12 Did I read that correctly? Do you see where I read?

13 A. Yes. The first line.

14 Q. And then I'm going to go down, skip a sentence and go to
15 "Approximately two years."

16 Are you there?

17 A. Yes.

18 Q. Approximately two years post filter placement, the patient
19 presented to the ER with chest pain. Imaging was performed,
20 and it was identified one of the filter limbs had broken off
21 and was in the patient's heart.

22 Now, did I read that correctly?

23 A. Yes.

24 Q. And, again, I'm showing you examples of how complaints were
25 generated, the types of complaints that Bard received. And you

1 agree that this is an example of a complaint whereby it was
2 reported to Bard that a patient with a G2 had a filter fracture
3 that went to the patient's heart. True?

4 A. Yes.

5 MR. O'CONNOR: And then if we go to the bottom,
6 Felice, we can show it's a G2.

7 BY MR. O'CONNOR:

8 Q. Can you see there, Mr. Modra, we're talking about a G2
9 filter?

10 A. Yes.

11 MR. O'CONNOR: And then, Felice, let's go to page 15.
12 And highlight that -- the first two lines, please.

13 What I want you to highlight, Felice, I'm sorry, is
14 "Definitive root causes unknown."

15 BY MR. O'CONNOR:

16 Q. And, again, when Bard and its people responsible for
17 complaints do these, they are supposed to look into doing a
18 root cause analysis; is that fair?

19 A. Yes.

20 Q. And that's to define what the issue is, which in this case
21 is a filter fracture; correct?

22 A. Correct.

23 Q. Analyze the situation. Here, a filter fracture went into a
24 patient's heart; correct?

25 A. Correct.

1 Q. And then determine what, if anything, can be done to the
2 design to prevent this. Correct?

3 A. As part of their root cause, that wouldn't be part of it.

4 Q. And this information, among other things, should show Bard
5 where there may be design flaws in its filters; true?

6 A. This is used collectively, with all the information from
7 complaints to determine if there is improvements that could be
8 made or other root causes, communication to customers,
9 et cetera.

10 Q. I think you'll agree with me, one area that these
11 complaints can be useful to Bard is showing Bard if its filters
12 have a design flaw or a defect in design that is harming
13 patients; true?

14 A. True.

15 Q. Thank you.

16 A. In this case, it noted --

17 Q. There's no --

18 A. -- you can't have a root cause because there were no images
19 and the device wasn't provided, so it makes it very difficult
20 to determine root cause.

21 MR. O'CONNOR: Move to strike as nonresponsive. He
22 had responded to the question.

23 THE COURT: Hold on just a minute.

24 Sustained. The jury should disregard the last answer.

25 MR. O'CONNOR: Would you show Exhibit 3304, please.

1 And let's go to page 2.

2 BY MR. O'CONNOR:

3 Q. A short description describes this as a filter arm
4 detachment.

5 Do you see that?

6 A. Yes.

7 Q. Another way that Bard would say the filter fractured in
8 this patient; correct?

9 A. Correct.

10 Q. And this complaint file was opened on July 28, 2010; true?

11 A. Yes.

12 MR. O'CONNOR: And if we go to page 3, Felice.

13 Highlight the first, probably, three sentences, Felice.

14 Oh, yes. I need to display this, Your Honor. I
15 apologize. Publish.

16 THE COURT: It's not in evidence, Mr. O'Connor.

17 MR. O'CONNOR: I move for admission of 3304.

18 MS. HELM: No objection subject to your prior order.

19 THE COURT: Admitted.

20 (Exhibit No. 3304 admitted into evidence.)

21 MR. O'CONNOR: All right. Thank you.

22 BY MR. O'CONNOR:

23 Q. And I see it and you see it, Mr. Modra. I just have to
24 make sure everybody else sees it.

25 THE COURT: Go ahead and publish it, Traci.

1 MR. O'CONNOR: Pardon me?

2 THE COURT: I was telling Traci to go ahead and
3 publish it. I'm honoring the request made before it was
4 admitted.

5 MR. O'CONNOR: Thank you.

6 BY MR. O'CONNOR:

7 Q. All right. I think now it is published for everyone to
8 see. You and I were looking at it.

9 It's reported on July 28, 2010; correct?

10 A. Correct.

11 Q. To a company representative, Chris Flair.

12 Did I read that correctly?

13 A. Correct.

14 Q. And there was a retrieval, and it was found that a filter
15 arm was missing from the filter.

16 Do you see that?

17 A. Yes, I do.

18 Q. And then the physician scouted for the filter limb, and it
19 was located in the patient's lung.

20 Do you see that?

21 A. Yes.

22 MR. O'CONNOR: And, Felice, if we go down to Product
23 Information on that page.

24 BY MR. O'CONNOR:

25 Q. This is an Eclipse filter that fractured and went into a

1 patient's lung; is that correct?

2 A. From the reported information, correct.

3 Q. Well, and certainly this is information that you at Bard
4 rely on as accurate; fair?

5 A. We write down and take in what people report to us as the
6 filter. But then upon receipt of that filter or additional
7 evidence, we confirm that it actually was that device.

8 Q. Sure.

9 So if you find additional evidence about anything, you
10 should supplement the report; correct?

11 A. Yes.

12 Q. You have to continually take steps to make sure that this
13 document is in the most accurate and thorough form; fair?

14 A. Correct.

15 Q. Because it's useful for Bard for, among other reasons, to
16 determine if there is a design flaw in a filter, true, among
17 other reasons?

18 A. Amongst other reasons.

19 Q. And it's also mandated by Bard so that if the FDA needs to
20 see these, it needs to be accurate for the FDA; true?

21 A. Correct.

22 Q. And that's an important responsibility; correct?

23 A. It is a very important responsibility.

24 Q. To make sure you're gathering accurate information and
25 reporting it to MAUDE database accurately; right?

1 A. Correct, as well as tracking and trending.

2 Q. And, when possible --

3 MR. O'CONNOR: If you go to page 8, Felice.

4 BY MR. O'CONNOR:

5 Q. -- you will collect photographs when available. Is that
6 true?

7 A. Yes.

8 Q. And here you did have photographic evidence of the filter;
9 correct?

10 A. Correct.

11 Q. Do you know if the filter came to Bard for inspection?

12 A. I would have to review the file.

13 MR. O'CONNOR: All right. But if we go to page 14,
14 under Root Cause. Right up here, Felice, under FDA Device
15 Code.

16 BY MR. O'CONNOR:

17 Q. It says, "Root cause: Unable to determine the root cause
18 based upon available information."

19 Do you see that?

20 A. I do.

21 Q. Now, we've just talked about three examples; correct?

22 A. Yes.

23 Q. But you and I could identify the problem in each of those
24 three. That was where a limb fractured. Agreed?

25 A. That is -- that isn't the root cause. That's just the --

1 Q. It's part of the root cause?

2 A. -- failure.

3 Q. It's to identify the failure as part of the root cause;
4 right?

5 A. That wouldn't be what the root cause -- the root cause
6 would be something acting upon the device to cause that
7 failure.

8 Q. I understand that, but I thought we agreed that a root
9 cause analysis is a couple steps of a process. Number one, you
10 have to identify the events that happened; right?

11 A. You start with the identification of the information and
12 the situation that the device was in prior to the failure.

13 Q. And we've just seen three complaints where you and I and
14 the people at Bard were to identify three separate cases --
15 excuse me -- in which filter limbs fractured; right?

16 A. Yes.

17 Q. And we identified three cases where filter limbs embolized
18 to different parts of the patient's body; correct?

19 A. That's correct.

20 Q. We identified three cases where the limbs went somewhere
21 other than the vena cava, where they were supposed to remain
22 intact with the filter; true?

23 A. That's correct.

24 Q. And they went to places like a pulmonary artery; correct?

25 A. That's correct.

1 Q. And to get to the pulmonary artery, the limb has to go
2 through the heart; true?

3 A. Correct.

4 Q. And we also saw an example where the limb went to the heart
5 but didn't make it through; fair?

6 A. As reported, correct.

7 Q. So at least you and I could start a root cause analysis
8 right here in this courtroom because we've identified a problem
9 in three cases; true?

10 A. Just because you identify the problem doesn't mean you've
11 established the root cause of the failure.

12 Q. Different question.

13 You and I here at least took a step in the direction
14 of a root cause analysis; correct?

15 A. Data collection at the start, correct.

16 Q. And if you and I wanted to, if anybody at Bard wanted to,
17 they could say, Mr. Modra, get your team and find every
18 complaint that is like Exhibit 3304; true?

19 A. It depends on what manner you're speaking of, "just like
20 it."

21 Q. But you could find filter fractures that went to the heart
22 or lung if that is what you were instructed to do; correct?

23 A. Correct.

24 Q. And you could look at those fractures and then you could
25 determine and verify it was a limb that fractured; correct?

1 A. A limb or some other portion, correct.

2 Q. And then as you went through the root cause analysis, you
3 could have your engineers come in and analyze the situation and
4 maybe take a look back and do things like finite element
5 analyses to look at filter strength and how it was responding
6 to stresses and strains in the vena cava. True?

7 A. True, similar to the way it was done prior to launch and
8 submission.

9 Q. Well, no, I'm not talking about prior to launch. I'm
10 talking about when we're doing a root cause analysis, things
11 that could be done. You agree that you could do that?

12 A. You could, but in that case, finite element analysis
13 wouldn't be a good solution to determine it. That's usually
14 done ahead of time, not finding a root cause.

15 Q. Nothing would prevent an engineer from coming in and
16 looking at these failures and going back and doing a finite
17 element analysis of a Bard filter. Do you agree with that?

18 A. True. It wouldn't further getting to the root cause.

19 Q. I just want yes or no. Is that a possibility? Is that
20 something that could be done; yes or no?

21 A. That among many other things. And I'm sure that's what
22 they determined as part of their --

23 Q. And I agree --

24 A. -- estimate of root cause in this case.

25 Q. I agree there could be many other things that were done.

1 But what Bard should be doing is determining, can we analyze
2 all of these failures and can -- is there something we can do
3 to prevent this from happening in the future. That's a root
4 cause analysis; correct?

5 A. Correct. And each one of these was --

6 Q. That's all I asked you.

7 A. -- thoroughly investigated.

8 You said that we could be investigating it, and I was
9 responding that --

10 Q. I asked you --

11 A. -- we have investigated it.

12 THE COURT: Please don't interrupt the witness,

13 Mr. O'Connor.

14 MR. O'CONNOR: Well, I asked him --

15 THE COURT: Hold on. If you want him to say yes or
16 no, make that clear.

17 And if he says, "Answer yes or no," and if you can,
18 answer it yes or no. If you can't, tell him, "I can't answer
19 it yes or no."

20 THE WITNESS: Okay.

21 BY MR. O'CONNOR:

22 Q. And let me just try it again.

23 I thought you and I agreed that a root cause analysis
24 is something that's done when Bard receives a complaint like
25 the three we received.

1 A. Correct.

2 Q. And I thought you and I agreed that the elements of a root
3 cause analysis, in its most basic sense, is to define what
4 happened. Agreed?

5 A. That's the starting point.

6 Q. And you and I did that today; true?

7 A. Through some of the portion of the initial starting point,
8 correct.

9 Q. And the next part of a good root cause analysis is to
10 analyze the situation; fair? Correct?

11 A. Correct.

12 Q. And then the third part of a root cause analysis, the one
13 we're talking about that happens here at Bard in the complaint
14 file, is to determine what can be done, if anything, to prevent
15 the failure from happening in the future. Correct?

16 A. That wouldn't be part of the root cause analysis. That
17 would be part of a subsequent corrective action if it deemed
18 that.

19 Q. But you agree that the three elements are define, analyze,
20 and prevent; fair?

21 A. Yes.

22 Q. Thank you.

23 MR. O'CONNOR: Now -- you can take that down, Felice.

24 BY MR. O'CONNOR:

25 Q. Complaint investigation activities at Bard are a very

1 important function in post-market surveillance; true?

2 A. Correct.

3 Q. Post-market surveillance, that is, fielding complaints and
4 analyzing them, goes directly to patient safety; correct?

5 A. Patient experience and patient safety. It's part of the
6 bigger picture, post-market surveillance.

7 Q. Patient safety is at the heart of complaint investigation.
8 True?

9 A. Yes.

10 Q. And it's an important function that the FDA regulates Bard
11 about; correct?

12 A. Yes.

13 Q. Bard makes -- you are required to comply with the FDA
14 regulations and make sure that your complaints are complete,
15 thorough, and accurate; true?

16 A. True.

17 Q. And that you have correctly identified and distinguished a
18 malfunction versus a serious injury; fair?

19 A. True.

20 Q. You are also required --

21 THE COURT: Hold on, Mr. O'Connor.

22 (Court reporter clarification.)

23 MR. LOPEZ: "At Bard."

24 BY MR. O'CONNOR:

25 Q. At Bard, you are responsible to comply with the FDA

1 regulations and the requirements to be complete and accurate in
2 your complaint investigations; true?

3 A. Correct.

4 Q. And that includes, among other things, being able to
5 distinguish and identifying a failure that is a malfunction
6 versus a serious injury; true?

7 A. True, in accordance with their definitions. Correct.

8 Q. And also, you are required at Bard to have procedures in
9 which you can show that you are able to adequately evaluate a
10 root cause of a failure; correct?

11 A. Correct.

12 MR. O'CONNOR: Let's show Exhibit 1680.

13 MR. LOPEZ: 1680?

14 MR. O'CONNOR: 1680.

15 BY MR. O'CONNOR:

16 Q. Mr. Modra, you recognize Exhibit 1680; correct?

17 A. I do.

18 Q. It's a warning letter from the FDA; true?

19 A. True.

20 MR. O'CONNOR: Move for admission of Exhibit 1680,
21 Your Honor.

22 MS. HELM: Your Honor, 401 and 403.

23 THE COURT: Are you moving for admission of the entire
24 document?

25 MR. O'CONNOR: I have it in the form that we've

1 discussed. I can show you the form that I plan to admit it in.

2 THE COURT: Have you shown it to defense counsel? The
3 question is whether it's redacted in the manner we previously
4 discussed.

5 MS. HELM: Yes. That's not the basis of my objection.

6 THE COURT: Okay. Well, let's talk at sidebar about
7 the basis for your objection. I'm not understanding it.

8 (At sidebar on the record.)

9 THE COURT: Ms. Helm, go ahead.

10 MS. HELM: Your Honor, my basis of my objection is
11 Rule 401 and 403. There's no -- there's been no testimony or
12 evidence yet that makes this relevant. There are no -- there's
13 been no evidence of any rates or anything like that in the
14 case.

15 THE COURT: What do you mean, any rates?

16 MS. HELM: Well, Your Honor, in Jones, to go back, the
17 progression -- and I understand you ultimately admitted it in
18 Jones, and I recognize that. I think it's premature at this
19 point because I don't think there's been the foundation and the
20 evidence on which you based your ruling in Jones when you
21 ultimately admitted it.

22 And having gone back and looked at the timeline of
23 what occurred in Jones, you didn't admit it until after Bard
24 had addressed rates and input rates in the case.

25 THE COURT: Rates of what?

1 MS. HELM: I'm sorry. Rates of complication.

2 Adverse -- rates comparing adverse events, Your Honor. I
3 apologize.

4 THE COURT: Go on.

5 MS. HELM: I think it's premature at this point. I
6 don't think it's relevant.

7 I also don't think that this goes to the strict
8 liability of whether there's a safer alternative design or to
9 the conduct during the design of the product. And I don't see
10 how it has any relevance to causation.

11 THE COURT: Well, I'm not -- I'm not remembering or
12 understanding why Bard's introduction of information about
13 rates is foundation for the FDA warning letter.

14 MS. HELM: Your Honor, I have to confess that I didn't
15 fully understand that either, but that was the progression of
16 the ruling in Jones.

17 THE COURT: What are you relying on?

18 MS. HELM: I'm relying on information from the Jones
19 transcript that I have -- that we have summarized where it -- I
20 mean, where we followed the progression where it eventually
21 came in after a discussion on rates.

22 THE COURT: Well, at some point I gave an explanation.
23 I take it you haven't found that?

24 MS. HELM: Your Honor, it's in Docket 11256.

25 THE COURT: I've got that, don't I? Isn't that what I

1 referred to?

2 MS. HELM: That's the date that you eventually --

3 THE COURT: Let me look at this briefly.

4 11256 doesn't talk about the FDA warning letter. It
5 talks about the Modra complaint exhibits and Recovery cephalad
6 migration.

7 MS. HELM: Excuse me, Your Honor, the numbered
8 sentence 2.

9 THE COURT: Okay. That's not -- yeah, I say it but
10 that's not an explanation.

11 MS. HELM: It was tendered on -- that order was
12 entered on May 29th. It was tendered on May 17. And I'm
13 reading, admittedly, a summary of the transcript, but you said
14 there was not enough evidence yet to let it come in.

15 And then it was tendered again on May 22nd and again
16 on May 25th. So it -- and it was after a substantial amount of
17 evidence, so...

18 THE COURT: Okay. Hold on just a minute.

19 MS. HELM: I have a clean copy.

20 THE COURT: I'm not reading the notes.

21 Well, my memory is that I let this in last time after
22 Mr. Modra had testified, and I think in Jones much of the
23 testimony came in during the defense case on the extensive
24 complaint handling procedures that Bard had in place. And I
25 thought it was relevant then that the FDA had critiqued the

1 complaint handling procedures.

2 Mr. O'Connor has covered much of that ground with
3 Mr. Modra today on detailed complaint handling procedures. I
4 think that, as redacted, this FDA warning letter does not
5 violate Rule 403. The section that will come in, which is
6 section 3, I think, concerns complaint handling procedures.

7 And so I'm going to overrule the objection and allow
8 the redacted exhibit to come in.

9 MR. O'CONNOR: Thank you.

10 (End of discussion at sidebar.)

11 THE COURT: Thanks, ladies and gentlemen.

12 MR. O'CONNOR: Move for admission of Exhibit 1680,
13 Your Honor.

14 THE COURT: Admitted.

15 (Exhibit No. 1680 admitted into evidence.)

16 MR. O'CONNOR: May I publish?

17 THE COURT: You may.

18 MR. O'CONNOR: And, Felice, if you could highlight
19 the first paragraph.

20 BY MR. O'CONNOR:

21 Q. This talks about a number of inspections that -- well,
22 inspections that occurred; specifically, an inspection that
23 occurred at the Tempe facility on November 18, 2014. Correct?

24 A. That's correct.

25 MR. O'CONNOR: And then, Felice, if you could go down

1 to the sentence that begins "Warning letter."

2 BY MR. O'CONNOR:

3 Q. And based upon that inspection, you at Bard received this
4 warning letter that addressed violations found at your Bard
5 Peripheral Vascular facility located in Tempe, Arizona; is that
6 true?

7 A. That's correct.

8 MR. O'CONNOR: Felice, let's go to page 4. Go to
9 number 3 there, Felice, and if you could just highlight and
10 pull out that first sentence.

11 Go ahead and go to the second sentence, too, please.

12 All the way -- might as well do the whole paragraph. And I can
13 summarize this with Mr. Modra, I believe.

14 BY MR. O'CONNOR:

15 Q. A violation that the FDA found, Mr. Modra, was that Bard
16 had failed to establish and maintain procedures for receiving,
17 reviewing, and evaluating complaints. Correct?

18 A. That's what they say. That's pretty standard language.

19 Q. Sir, that's what the warning letter that came to Bard said;
20 true?

21 A. Yes. And I'm familiar that it's present in most warning
22 letters related to complaint handling.

23 Q. Well, I'm not talking about most, and I don't know how many
24 others you've received. I'm talking about this.

25 When this came to Bard --

1 THE COURT: Excuse me, Mr. O'Connor. Don't comment on
2 the answer. Just ask a question, please.

3 BY MR. O'CONNOR:

4 Q. All right. This came to Bard and it eventually came to
5 you; true?

6 A. Correct.

7 Q. And it was a warning letter from the FDA; correct?

8 A. That's correct.

9 Q. And the warning letter addressed, among other things, your
10 failure to maintain procedures for reviewing -- receiving,
11 reviewing, and evaluating complaints; true?

12 A. That is what it says, and it gives details below.

13 Q. All right. Well, let's look at what it says there.

14 It says: Your current procedures governing complaint
15 investigations --

16 MR. O'CONNOR: Still stay at that paragraph 3, still
17 staying at the above paragraph.

18 BY MR. O'CONNOR:

19 Q. You see where I'm reading from? It starts out: "Your
20 current procedures governing complaint activities at your
21 facilities," and then it goes through standards.

22 Do you see where I read?

23 A. Yes, I do.

24 Q. And at the end of that sentence, it says, "do not ensure
25 product complaints are adequately evaluated."

1 Now, did I read that correctly?

2 A. Yes.

3 Q. Thank you.

4 MR. O'CONNOR: All right, Felice. Let's go down.

5 BY MR. O'CONNOR:

6 Q. And then subparagraph a talks about the Tempe Bard
7 Peripheral Vascular procedures governing complaint
8 investigations; correct?

9 A. Correct.

10 MR. O'CONNOR: And then, Felice, that -- highlight
11 from "Complaint investigation procedures."

12 BY MR. O'CONNOR:

13 Q. And the warning or the inspection by FDA found that
14 complaint investigation procedures do not include adequate
15 instructions for ensuring that complaints involving a device or
16 device component provided by a supplier are adequately
17 evaluated for root cause of the alleged device failure and that
18 appropriate corrective action is implemented with your
19 suppliers.

20 Now, did I read that correctly?

21 A. That's correct.

22 Q. And if we go down to subsection b.

23 And this section deals with complaints that were filed
24 as malfunctions that should have been filed as serious
25 injuries.

1 Do you see where I'm reading from, Mr. Modra?

2 A. Yes, I do.

3 Q. And they note a complaint about an Eclipse filter with a
4 detached filter limb resulted in pericardial effusion and
5 cardiac catheterization.

6 Do you see where I read?

7 A. I see that.

8 Q. And then it talks about a G2 Express -- go to the next --
9 with a filter -- broken filter and surgical intervention.

10 Did I read that correctly?

11 A. Correct.

12 Q. And then another complaint that was discussed.

13 MR. O'CONNOR: Look at the next G2 filter, Felice.

14 BY MR. O'CONNOR:

15 Q. A G2 filter limb in the renal vein -- a detached filter
16 limb in the renal vein with the IVC wall perforation and blood
17 thinner treatment.

18 Did I read that correctly?

19 A. Correct.

20 Q. The next is a G2 Express filter with IVC perforation and
21 aneurysm.

22 See that?

23 A. Yes.

24 Q. The next is a G2 filter with abdominal pain with filter
25 legs protruding through the IVC wall and percutaneous removal.

1 Did I read that correctly?

2 A. Yes.

3 Q. And then there was a G2 filter, abdominal pain with filter
4 legs penetrating IVC wall, and then it talks about partial
5 retrieval and residual filter leg fragment embedded in IVC
6 wall.

7 Did I read that correctly?

8 A. Yes.

9 Q. And those were all part of subparagraph b, which discussed
10 Bard's filing of these complaints as malfunctions as opposed to
11 serious injuries; true?

12 A. Correct.

13 Q. Thank you.

14 MR. O'CONNOR: And then let's go to paragraph c,
15 Felice.

16 BY MR. O'CONNOR:

17 Q. And there were a number of complaints involving at least
18 ten patients that the FDA included in part of this warning
19 letter; is that right?

20 A. It lists eight complaints.

21 Q. I see the numbers, and it says: Report at least ten
22 patients who were exposed to schedule retrieval surgical
23 procedures to remove an IVC filter that were not successful.

24 Did I read that correctly?

25 A. Yes.

1 Q. But what the FDA said in its warning: However, these
2 complaint files do not document sufficient information to allow
3 for adequate complaint investigation and disposition,
4 including, but not limited to, MDR determination.

5 Did I read that correctly?

6 A. Yes.

7 Q. For example, the FDA warned you, the complaints do not
8 include information regarding prolonged or repeated surgery
9 that may have occurred as a result of failed attempts to remove
10 filters, information regarding why filters were scheduled to be
11 removed, and potential complications to leaving them in the
12 patient due to failed removal and/or if any additional drugs or
13 anesthetics had to be supplied to the patients.

14 Did I read that correctly?

15 A. Yes.

16 Q. And you, at Bard, were required to take prompt action to
17 correct these; true?

18 A. True.

19 Q. Thank you.

20 MR. O'CONNOR: Let's go to Exhibit 4515.

21 Your Honor, may I show Mr. Modra a part of an exhibit?
22 It's Exhibit 4515 at page 12. I just --

23 THE COURT: What are you asking?

24 MR. O'CONNOR: I would like to approach him and
25 identify what we're looking at.

1 THE COURT: Why approach him? Can't you put it on the
2 screen?

3 MR. O'CONNOR: Well, I think I have to put it on the
4 ELMO, because I've just learned that our computer won't show
5 this in a form that we need.

6 THE COURT: Do we have a paper copy of the exhibit,
7 including a copy for defendant?

8 I think we need to have the full exhibit in order to
9 ask questions.

10 MR. O'CONNOR: It's Exhibit 4515.

11 May I display this page to the witness, Your Honor?

12 THE COURT: On the ELMO?

13 MR. O'CONNOR: Yes.

14 THE COURT: Yes.

15 Traci, could you do it just to the witness?

16 MS. HELM: I'm sorry, what page is that?

17 MR. O'CONNOR: It's going to be page 12.

18 MS. HELM: Thank you.

19 MR. O'CONNOR: Right here.

20 BY MR. O'CONNOR:

21 Q. All right. Mr. Modra, are you able to see Exhibit 4515 at
22 page 12?

23 A. Yes.

24 Q. It is part of a monthly management report dated April 10,
25 2010. You know what those are; correct?

1 A. Monthly management reports?

2 Q. Yes.

3 A. Yes.

4 Q. And you recall that information from the complaint files,
5 the summaries, are used for other purposes in Bard, including
6 in monthly management reports; correct?

7 A. That's correct.

8 Q. And so if you look at the highlighted section, I think you
9 agree that that's consistent with the type of summaries that
10 are included in your complaint files; fair?

11 A. Correct.

12 MR. O'CONNOR: At this time, Your Honor, I would move
13 for admission of Exhibit 4515, and specifically, the pages that
14 have the summaries. I think we can deal with that.

15 THE COURT: What pages are those?

16 MR. O'CONNOR: It looks like it's on page 12 and
17 page 13.

18 THE COURT: All right. So you're moving for pages 12
19 and 13 of Exhibit 4515?

20 MR. O'CONNOR: Yes, Your Honor.

21 THE COURT: Any objection?

22 MS. HELM: Yes, Your Honor. No foundation.

23 THE COURT: What's the foundation that's missing?

24 MS. HELM: Your Honor, he hasn't laid a foundation to
25 this -- he's shown him one page of the document. He hasn't

1 shown him the document in context.

2 THE COURT: Well, I guess the question is, foundation
3 typically goes to authenticity. Are you concerned that it's --

4 MS. HELM: No, Your Honor.

5 THE COURT: -- not a monthly management report?

6 MS. HELM: No, Your Honor, but I just don't think
7 that's been established. I mean, he's just shown him one
8 portion of the document.

9 THE COURT: Well, you're not disputing the
10 authenticity?

11 MS. HELM: No, Your Honor.

12 THE COURT: All right. The objection is overruled.

13 Pages 12 and 13 of 4515 will be admitted.

14 (Exhibit No. 4515, pages 12 and 13, admitted into
15 evidence.)

16 BY MR. O'CONNOR:

17 Q. And, Mr. Modra, may I publish --

18 MR. O'CONNOR: First of all, Your Honor, may I publish
19 to the jury?

20 THE COURT: Well, not with -- well, do you have
21 handwriting on it?

22 MR. O'CONNOR: I have a highlight on it.

23 THE COURT: Okay.

24 MS. HELM: The exhibit on the exhibit list is not
25 highlighted.

1 THE COURT: Well, I understand that. I take it the
2 exhibit isn't highlighted.

3 This is just your highlighting like you'd do with the
4 computer; is that right?

5 MR. O'CONNOR: It's my highlighting just to help
6 display it.

7 THE COURT: You can do it with the computer in the
8 same manner, so you can display page 12.

9 MR. O'CONNOR: Thank you.

10 BY MR. O'CONNOR:

11 Q. Now, Mr. Modra, when we talked about earlier different ways
12 that complaint files are used, more specifically, to summarize
13 information, this is one way at Bard that this information is
14 used; correct?

15 A. Correct.

16 Q. And every month to the management board and to the
17 president and vice president, they receive a report which
18 includes summaries of complaints received in a given period of
19 time; fair?

20 A. Certain complaints, yes.

21 Q. And here, for example -- and those are reports that just go
22 to management, nobody else within Bard; true?

23 A. They're amongst the board, local management board.

24 Q. They're not reports that would go to engineering or sales,
25 for example; correct?

1 A. No.

2 Q. You agree with that?

3 A. I agree.

4 Q. All right. And if we look at just an example for the
5 members of the jury, we can see here where we are looking at
6 the highlighted one. And it is a detachment of a filter limb
7 for a G2 filter; correct?

8 A. Correct.

9 Q. And you are -- you know that summaries for the G2, the G2X,
10 and the Eclipse all can be obtained from the complaint reports
11 that you and I talked about today; correct?

12 A. That's correct.

13 Q. And we just talked about three complaints, but I imagine
14 you have hundreds or thousands of complaints within Bard; fair?

15 A. Within all of Bard, yes.

16 Q. And out here in Tempe, you have hundreds or thousands?

17 A. Correct, across all product lines.

18 MR. O'CONNOR: Thank you.

19 That's all the questions I have, Your Honor.

20 THE COURT: All right. Cross-examination?

21 MS. HELM: Yes, Your Honor.

22 CROSS-EXAMINATION

23 BY MS. HELM:

24 Q. Good afternoon, Mr. Modra.

25 I want to start with just some questions about the FDA

1 warning letter that was just discussed with you with
2 Mr. O'Connor.

3 As part of the FDA warning letter -- and we'll get
4 into it in more detail -- was there any instance where the FDA
5 claimed or found that Bard had failed to report any injury from
6 an IVC filter to the FDA?

7 A. No.

8 Q. Was there any claim by the FDA that Bard failed to report
9 any fracture of an IVC filter to the FDA?

10 A. No.

11 Q. Was there any claim by the FDA that Bard failed to report
12 any instance of migration of an IVC filter to the FDA?

13 A. No.

14 Q. Was there any claim by the FDA that Bard failed to report
15 any instance of the tilt of an IVC filter to the agency?

16 A. No.

17 Q. Was there any claim by the FDA that Bard failed to report
18 any instance of perforation of an IVC filter to the agency?

19 A. No.

20 Q. Regardless of whether Bard reported these adverse events to
21 the FDA as a malfunction or a serious injury, they were all
22 reported to the FDA; correct?

23 A. Yes.

24 Q. And all of these adverse events -- migration, fracture,
25 tilt, and perforation -- were always included in Bard's

1 tracking and trending analysis; correct?

2 A. Correct. Regardless of reportability, they're all tracked
3 and trended based on failure mode.

4 MS. HELM: Your Honor, we'll reserve the rest of our
5 questions for Mr. Modra to our case in chief. Thank you.

6 THE COURT: All right. Any redirect?

7 REDIRECT EXAMINATION

8 BY MR. O'CONNOR:

9 Q. The FDA doesn't design Bard filters, does it --

10 A. No.

11 Q. -- that's Bard?

12 A. Not to my knowledge, no.

13 Q. The FDA doesn't manufacture your filters, do they?

14 A. No, sir.

15 MS. HELM: Your Honor, objection. Exceeds the scope
16 of the cross.

17 THE COURT: Sustained.

18 BY MR. O'CONNOR:

19 Q. The FDA can only review reports that are prepared by Bard,
20 right, when it comes to Bard?

21 A. They can review any reports that we have. They conduct
22 investigations on site.

23 Q. But the FDA relies on an honor system; true?

24 A. An honor system that is verified by on-site inspections by
25 them.

1 Q. The FDA needs to rely that Bard is providing accurate and
2 truthful information; correct?

3 A. Correct. They start with that, but they verify that by
4 on-site inspections.

5 Q. Well, I'm not asking about verification. I'm just talking
6 about what the FDA has a right to expect from Bard. Do you
7 understand that's the scope of my question?

8 A. I understand.

9 Q. The FDA has a right to expect that Bard will provide
10 accurate and truthful information; true?

11 A. Correct.

12 Q. And tracking and trending is something that Bard does
13 internally; fair?

14 A. Correct.

15 MR. O'CONNOR: That's all I have.

16 THE COURT: All right. Thanks, Mr. Modra. You can
17 step down.

18 (Witness excused.)

19 MS. REED ZAIC: Apologize to the Court. We're loading
20 the video. By the time I'm finished reading this, it should be
21 done.

22 The next witness that will be appearing by videotape
23 is Dr. Ciavarella, spelled C-I-A-V-A-R-E-L-L-A.

24 Dr. Ciavarella obtained his medical degree from UCLA,
25 then completed an internship and residency at Roosevelt

1 Hospital in New York City, followed by a fellowship in
2 hematology at the University of Washington.

3 Dr. Ciavarella joined C.R. Bard in 2004 as vice
4 president of corporate clinical affairs. In that role,
5 Dr. Ciavarella originally had responsibilities over both
6 clinical affairs, which oversees clinical trials, and medical
7 affairs, which provides the medical component to the quality
8 system and informs risk analyses.

9 In 2008, Dr. Ciavarella's role in clinical affairs
10 grew to the point that medical affairs was transitioned to
11 another individual.

12 Since 2004, Dr. Ciavarella's work has included BPVs,
13 IVC filters, including the Recovery and G2 filters.

14 And the exhibit conversion is deposition Exhibit No. 8
15 will be trial Exhibit 2057; Exhibit 21 will be trial
16 Exhibit 1256 -- I beg your pardon -- 1216; deposition
17 Exhibit 22 will be trial Exhibit 922; deposition Exhibit 24
18 will be trial Exhibit 923; deposition Exhibit 26 will be trial
19 Exhibit 924; deposition Exhibit 27 will be trial Exhibit 1940;
20 deposition Exhibit 28 will be trial Exhibit 925; deposition
21 Exhibit 33 will be trial Exhibit 991; deposition Exhibit 35
22 will be trial Exhibit 927; deposition Exhibit 39 will be trial
23 Exhibit 931; and deposition Exhibit 40 will be trial
24 Exhibit 1221.

25 And I'd like to move these exhibits into evidence,

1 Your Honor.

2 MS. HELM: Your Honor, some of these exhibits require
3 redactions subject to your prior rulings. And the exhibits
4 provided to us were not redacted, and I just want to make sure
5 that they're redacted before they're displayed or admitted.

6 MS. SMITH: We provided only exhibit numbers, and the
7 exhibit numbers that correspond with -- is redacted.

8 THE COURT: So they are redacted?

9 MS. SMITH: That's correct.

10 THE COURT: Okay. So you have no objection to their
11 redacted versions being admitted?

12 MS. HELM: Your Honor, it's hard for me to say because
13 I haven't seen the redacted version. But assuming that they're
14 redacted consistent with prior rulings, I have no objection to
15 that.

16 I haven't had the opportunity to review this
17 transcript. It came during the last witness, so I'm at a
18 little bit of a disadvantage on that.

19 THE COURT: Well, I'm going to admit it subject to
20 redaction. If you see something on the screen, Ms. Helm, that
21 you think is inconsistent with the prior rulings on redaction,
22 say so and we'll stop the videotape.

23 (Exhibit Nos. 2057, 1216, 922, 923, 924, 925, 991,
24 927, 931, 1221 admitted into evidence.)

25 THE COURTROOM DEPUTY: 1940 was already admitted.

1 THE COURT: Traci also notes that Exhibit 1940 was
2 previously admitted into evidence, so that's already in.

3 MS. REED ZAIC: Thank you. And we are creating a
4 running list for the jury and the Court at the end of it all.

5 THE COURT: Okay. Thank you.

6 You can go ahead and play the deposition.

7 (Video deposition played.)

8 THE COURT: Let's stop the video there.

9 All right, ladies and gentlemen, we'll break until
10 2:45. We'll excuse the jury at this time.

11 MS. HELM: Your Honor, may we address something before
12 you leave?

13 (Jury not present.)

14 THE COURT: Go ahead, Ms. Helm.

15 MS. HELM: Your Honor, there were two exhibits,
16 Exhibit 927 and Exhibit 931, both of which stayed on the screen
17 for quite a while and both of which referred to another lawsuit
18 pending in the Superior Court of Maricopa County and have the
19 civil action file number.

20 Those were the specific redactions that I was
21 referring to that was reported to us that they had been made.
22 So the jury's been up there looking at a document showing that
23 it was admitted or subject to another lawsuit in two different
24 exhibits.

25 THE COURT: What are you requesting?

1 MS. HELM: Your Honor, I don't know at this point what
2 we request. I have to make a record on it. I was catching it
3 as the video was going, and I'd like the opportunity to confer
4 with counsel.

5 THE COURT: Okay. You can confer.

6 (Recess taken, 2:30 p.m. to 2:45 p.m.)

7 (Jury present.)

8 THE COURT: All right. Let's continue.

9 (Video deposition played.)

10 MR. LOPEZ: That concludes that testimony.

11 MR. O'CONNOR: We will call Mr. Robert Carr at this
12 time.

13 THE COURT: If you want to stand up, ladies and
14 gentlemen, while he's coming in, feel free.

15 THE COURTROOM DEPUTY: Mr. Carr, if you'll please come
16 forward.

17 Sir, if you'll please stand right there and raise your
18 right hand.

19 (The witness was sworn.)

20 THE COURTROOM DEPUTY: Please state your name and
21 spell it for the record, sir.

22 THE WITNESS: Robert Michael Carr Jr., C-A-R-R.

23 THE COURTROOM DEPUTY: Thank you. Please come have a
24 seat.

1 ROBERT MICHAEL CARR JR.,
2 called as a witness herein by the plaintiffs, having been first
3 duly sworn or affirmed, was examined and testified as follows:

4 DIRECT EXAMINATION

5 BY MR. O'CONNOR:

6 Q. Hello, Mr. Carr. My name's Mark O'Connor. I think we've
7 met before.

8 A. Hello.

9 Q. And let's start out with your background.

10 You are the vice president of international at Bard
11 Peripheral Vascular?

12 A. Yes, I am.

13 Q. And prior to that, or until October of 2015, you were the
14 senior director of research and development at Bard; true?

15 A. I was.

16 Q. And prior to that time, you were with a company called
17 Nitinol Medical Technologies; is that right?

18 A. Prior to coming to Bard, yes.

19 Q. And I think you came to Bard in 2002?

20 A. That's correct.

21 Q. And at Nitinol Medical Technologies, otherwise known as
22 NMT, you were responsible for IVC filters; fair?

23 A. Partially, yes.

24 Q. And at Bard, as part of your -- the course of your work,
25 you are familiar with documentation and records associated with

1 the design, the development, manufacture, regulatory
2 compliance, and testing of Bard IVC filters; true?

3 A. I'm familiar with some.

4 Q. You are also familiar with Bard's recordkeeping procedures;
5 correct?

6 A. Yes.

7 Q. Thank you.

8 I want to start today talking to you about caudal
9 migration and the caudal migration push test.

10 You agree that caudal migration is an undesirable
11 complication; true?

12 A. I think all complications are relatively undesirable.

13 Q. Sir, I'm talking about caudal migration. Do you agree that
14 it is undesirable and that you've testified to that before?

15 A. I don't know that I've testified to it, but yes, I agree.

16 Q. Well, let's make sure you know that.

17 MR. O'CONNOR: Let's go to page 689 of the May
18 trial -- excuse me, the May transcript.

19 BY MR. O'CONNOR:

20 Q. And if you look at 689, 9 to 15, sir, and the last part of
21 that question was: Caudal migration is not a desirable
22 complication with any filter. True?

23 And your answer was: Yes.

24 Did I read that correctly?

25 A. Yes.

1 Q. Thank you.

2 To put it simply, a filter that is migrating caudally
3 downward is not staying in place; correct?

4 A. If it migrates more than 2 centimeters, yes.

5 Q. Do you agree with me that a filter that migrates caudally
6 downward is not staying in place?

7 A. Again, only if it moves more than 2 centimeters downward.

8 MR. O'CONNOR: Let's go to 689, please. Line 21 to
9 24.

10 BY MR. O'CONNOR:

11 Q. The question to you, sir, was: And when a device migrates
12 caudally, it means it's not staying where it was put. It shows
13 some signs of instability. Would you agree?

14 Your answer was: Yes.

15 Now, did I read that correctly, sir?

16 A. Yes.

17 Q. Thank you.

18 Prior to launch, do you agree that Bard did not
19 conduct bench tests of the G2 filter to compare caudal
20 migration with the Simon Nitinol filter or other filters?

21 A. Yes.

22 Q. And in response to increasing reports of G2 caudal
23 migration, Bard developed a test for caudal migration; correct?

24 A. We developed it due to reports, yes.

25 Q. You developed a test; true?

1 A. Yes.

2 Q. Thank you.

3 MR. O'CONNOR: Felice, let's show Mr. Carr
4 Exhibit 1578.

5 BY MR. O'CONNOR:

6 Q. And, Mr. Carr, you recognize this exhibit?

7 A. Yes.

8 MR. O'CONNOR: Move to admit Exhibit 1578.

9 MR. ROGERS: No objection, Your Honor.

10 THE COURT: Admitted.

11 (Exhibit No. 1578 admitted into evidence.)

12 MR. O'CONNOR: May I publish to the jury?

13 THE COURT: Yes.

14 BY MR. O'CONNOR:

15 Q. And this is a caudal migration test method development and
16 G2 filter resistance test project?

17 A. It's a report.

18 Q. Test report. Thank you.

19 And you see that it's approved on November 27, 2006?

20 A. Thank you. Yes.

21 MR. O'CONNOR: Felice, go to page 3.

22 BY MR. O'CONNOR:

23 Q. And, sir, looking at Purpose and Objective, do you see that
24 top part?

25 MR. O'CONNOR: Felice, if you could pull that part

1 out.

2 THE WITNESS: Yes.

3 BY MR. O'CONNOR:

4 Q. The objective of this study was to evaluate multiple caudal
5 migration resistance test methods and then use these test
6 methods to evaluate caudal migration resistance of the G2
7 filter versus commercially available filters.

8 Did I read that correctly?

9 A. Yes. We were trying to develop a test.

10 Q. Did I read it correctly, sir?

11 A. Yes.

12 Q. Thank you.

13 The G2 filter was compared against the Greenfield,
14 Gunther Tulip, OptEase, Simon Nitinol, and Recovery filters.

15 Did I read that correctly; yes or no?

16 A. Yes.

17 Q. Thank you.

18 MR. O'CONNOR: Felice, if you could go down the page,
19 the third paragraph under Background.

20 BY MR. O'CONNOR:

21 Q. Were you involved in preparing this report?

22 A. No, I don't believe so.

23 Q. Was there people from Bard that were involved in the
24 preparation of this report?

25 A. Yes.

1 MR. O'CONNOR: First sentence, Felice.

2 THE WITNESS: Sorry?

3 BY MR. O'CONNOR:

4 Q. I'm just trying to highlight something for you and show it
5 to you, sir. And I'm going to read this sentence to you. You
6 tell me if I read it correctly as part of this report.

7 The G2 filter has had recent complaints related to
8 caudal migration resistance.

9 Did I read that correctly, sir?

10 A. Yes.

11 Q. Thank you.

12 So the test was going to involve the G2 filter, the
13 Simon Nitinol filter, the Recovery filter, and some competitor
14 filters?

15 A. This is a report to develop tests; but, yes, it tested
16 them.

17 Q. Thank you.

18 MR. O'CONNOR: Felice, let's go to page 13.

19 BY MR. O'CONNOR:

20 Q. We're looking at a graph at the top, Figure 2.

21 Do you see that, Mr. Carr?

22 A. Yes.

23 Q. And that -- the title of this graph is Caudal Migration
24 Push Test Average Results.

25 Do you see where I read from?

1 A. Yes.

2 Q. And then you have at the right, different letters.

3 O stands for OptEase; is that fair?

4 A. Yes.

5 Q. SNF is the Simon Nitinol filter; correct?

6 A. Yes.

7 Q. T is the Gunther Tulip?

8 A. Maybe the TrapEase. I don't know which off the top of my
9 head.

10 Q. All right. RF is the Recovery?

11 A. Yes.

12 Q. G2 is the Bard G2 filter?

13 A. Yes.

14 Q. And what is G?

15 A. Greenfield.

16 Q. Thank you.

17 And the bottom line, that refers to the peak load on
18 these filters for migration push?

19 A. I'm sorry?

20 Q. The bottom line refers to the average peak load; is that
21 correct?

22 A. No.

23 Q. What does the bottom line refer to?

24 A. The bottom line? I'm sorry, I don't understand what "the
25 bottom line" is.

1 Q. There's a line there that talks about -- aren't you
2 measuring here the amount of load to make the device move
3 downward?

4 A. Yes.

5 Q. And the Greenfield took the minimum amount of load to move
6 downward; is that correct?

7 A. Yes.

8 Q. And the G2 was next; correct?

9 A. Yes.

10 Q. The G2 was worse than the Recovery filter in terms of
11 caudal migration, the test; true?

12 A. In certain diameters.

13 Q. Is that correct? The G2 was worse?

14 A. In certain diameters, yes.

15 Q. The G2 was worse than the Tulip?

16 A. I don't know if that's the Tulip or the TrapEase.

17 Q. Let's assume it was the Tulip and that you've testified
18 that before.

19 The G2, regardless of what it was, was worse than the
20 T filter; right?

21 A. Yes.

22 Q. And the G2 was worse than the Simon Nitinol filter;
23 correct?

24 A. Yes.

25 Q. And the Simon Nitinol filter was the predicate to the

1 Recovery device; correct?

2 A. One of them, yes. The other one being the Greenfield.

3 Q. The G2 was worse than the OptEase; true?

4 A. Yes.

5 Q. Now, after the G2 came the G2X; is that right, Mr. Carr?

6 MR. O'CONNOR: We can take that down, Felice.

7 THE WITNESS: Yes.

8 BY MR. O'CONNOR:

9 Q. And the Eclipse did not improve caudal migration --

10 And then after the G2X came the Eclipse; true?

11 A. Yes.

12 Q. And the Eclipse did not improve caudal migration

13 resistance; correct?

14 A. Improve it over what?

15 Q. Over the G2 or the G2X.

16 A. No, it did not.

17 Q. Physicians were not aware of the testing that was done at
18 Bard; true?

19 A. Physicians are aware of some of the testing done at Bard.

20 Q. They weren't aware of the caudal push test that we're
21 talking about, were they?

22 A. Some were.

23 MR. O'CONNOR: Let's go to page 695 of the prior
24 testimony.

25 694, Felice. I'm sorry.

1 BY MR. O'CONNOR:

2 Q. I apologize, Mr. Carr. My notes must be wrong because I
3 don't see the testimony I was referring to. I'll move on.

4 Bard did not add caudal anchors or hooks to the
5 Eclipse; is that correct?

6 A. We did add them to the Eclipse. It became the Meridian
7 filter.

8 Q. But when the Eclipse came on the market, it did not have
9 caudal anchors or hooks; fair?

10 A. Yes.

11 MR. O'CONNOR: Felice, let's show Mr. Carr
12 Exhibit 4409.

13 BY MR. O'CONNOR:

14 Q. Sir, this is the brochure for the G2 system for permanent
15 placement; is that correct?

16 A. Yes, it is.

17 MR. O'CONNOR: Move to admit Exhibit 4409.

18 MR. ROGERS: No objection, Your Honor.

19 THE COURT: Admitted.

20 (Exhibit No. 4409 admitted into evidence.)

21 BY MR. O'CONNOR:

22 Q. And, again, this is the G2. The G2 was promoted as a
23 permanent filter; correct?

24 A. At first, yes.

25 Q. And it remained a permanent filter the entire time it was

1 on the market; true?

2 A. With the option to remove, yes.

3 MR. O'CONNOR: May I publish Exhibit 4409?

4 THE COURT: Yes.

5 BY MR. O'CONNOR:

6 Q. Now, this is messaging that was approved by corporate, Bard
7 corporate; correct?

8 A. If you show me the rest of it, I can --

9 Q. Sure.

10 MR. O'CONNOR: Will you go to the next page?

11 BY MR. O'CONNOR:

12 Q. Do you want to go to the next page?

13 A. The last page.

14 Q. Go to the last page.

15 A. I can't read it, but yes.

16 Q. Thank you.

17 MR. O'CONNOR: And, Felice, let's go to page 2.

18 BY MR. O'CONNOR:

19 Q. And this is information, a brochure, that ultimately was
20 intended for the medical community, the customers of the
21 filter; is that correct?

22 A. Yes.

23 Q. And Bard contended that the G2 filter was taking strength
24 and stability to a new level.

25 Do you see where I read?

1 A. Yes.

2 Q. Strength means, in part, that the filter will not break;
3 true?

4 A. I don't know. I think more migration when I hear
5 "strength," but -- regarding hook strength.

6 Q. Well, let's just go to 697 of your testimony, sir.

7 And if you look at line 19 at page 697 -- are you with
8 me?

9 A. Yes.

10 Q. And it says: And strength, again, is it won't break?

11 And your answer was: Partially.

12 Did I read that correctly?

13 A. Yes, you did.

14 Q. And then: Stability means it's going to stay where you put
15 it?

16 And your answer was: Right.

17 Did I read that correctly?

18 A. Yes.

19 Q. And so when Bard was representing that the G2 filter was
20 taking strength and stability to a new level, it intended that
21 message to mean that it was strong in terms, in part, that the
22 filter would not break; and in stability, it meant that the
23 filter was designed to stay in place in the vena cava. True?

24 Strength and stability?

25 A. Yes.

1 Q. Thank you.

2 MR. O'CONNOR: Let's see Exhibit 4409, Felice.

3 Okay. Let me look at Exhibit 4430.

4 BY MR. O'CONNOR:

5 Q. Mr. Carr, I'm trying to find the G2X brochure, but let me
6 ask you this, just so we're clear, coming from you and your
7 position at Bard.

8 G2X and G2 Express are the same filter; correct?

9 A. Yes, they are.

10 Q. Let's go to 16 -- oh, here we go.

11 And this is Exhibit 4438. This is a promotional
12 brochure for the G2 Express; correct?

13 A. Yes.

14 MR. O'CONNOR: Move for admission of 4438.

15 MR. ROGERS: No objection, Your Honor.

16 THE COURT: Admitted.

17 (Exhibit No. 4438 admitted into evidence.)

18 MR. O'CONNOR: Let's go to Exhibit 1616, Felice.

19 May I publish this one, Your Honor, before we move?

20 THE COURT: You may.

21 MR. O'CONNOR: And can we go back to 4409? I don't
22 believe I published that one to the jury. May I publish this
23 to the jury, Your Honor?

24 THE COURT: You may.

25 MR. O'CONNOR: And, Felice, can you go to the page

1 where we discussed strength and stability to a new level, and
2 can you blow that up?

3 BY MR. O'CONNOR:

4 Q. Those are the words we talked about a moment ago; correct,
5 Mr. Carr? Strength and stability?

6 A. Yes.

7 Q. Thank you.

8 A. Uh-huh.

9 MR. O'CONNOR: Now let's go to 4430, Felice.

10 BY MR. O'CONNOR:

11 Q. 4430 is a patient brochure for the Eclipse filter; is that
12 correct?

13 A. I see the cover, if you could show me the rest.

14 Q. Do you want to see the next page?

15 A. The back page, primarily.

16 Q. You want to go to the end?

17 A. Yes. Thank you.

18 Q. Do you need anything enlarged?

19 A. No.

20 Q. Is this the brochure that was disseminated to doctors?

21 A. It was a brochure that was made, yes. I'm sure it was
22 given to some doctors.

23 MR. O'CONNOR: Move to admit 4430.

24 MR. ROGERS: No objection, Your Honor.

25 THE COURT: Admitted.

1 (Exhibit No. 4430 admitted into evidence.)

2 MR. O'CONNOR: And may we publish and just scroll --
3 excuse me. Move to admit --

4 4430, Felice. I'm throwing you off. I apologize.
5 And, Felice, can you just scroll through the pages so that the
6 jury can see the brochure for the Eclipse?

7 Go back. Let's just go a little bit slower. Go to
8 the --

9 THE COURT: It's not published, Mr. O'Connor.

10 MR. O'CONNOR: Oh. May we publish, Your Honor?

11 THE COURT: You may.

12 MR. O'CONNOR: All right. Go to page 2, Felice.

13 BY MR. O'CONNOR:

14 Q. And here, Mr. Carr, the Eclipse filter, according to this
15 brochure, is represented by Bard as the first choice in IVC
16 filters, now with an enhanced finish.

17 Do you see where I read?

18 A. Yes.

19 Q. And it goes on to say: The electropolished Eclipse vena
20 cava filter combines proven performance with long-term
21 retrievability and improved fracture resistance.

22 Correct?

23 A. Yes.

24 MR. O'CONNOR: Go to the next page, Felice.

1 BY MR. O'CONNOR:

2 Q. And what was done was, essentially the Eclipse is very
3 similar to the G2X; right?

4 A. It is similar in its shape. It is very different in how
5 it's made and ultimately got to that shape.

6 Q. Do you agree it's similar to the G2X?

7 A. I think that's a relative term. I think, as I said, the
8 manufacturing processes are very, very different from the G2X
9 and --

10 Q. Well --

11 A. -- ultimately it looks similar.

12 Q. The change was electropolishing; correct?

13 A. The change was electropolishing, which is an incredibly
14 significant change in how the actual filter is made.

15 Q. Sir, my question is just simple yes or no: Was the change
16 electropolishing, yes or no?

17 A. I can't answer that question yes or no.

18 Q. Let's look at your testimony at 702, please.

19 MR. O'CONNOR: And will you go to 703, Felice.

20 BY MR. O'CONNOR:

21 Q. And we were talking about the Eclipse, Mr. Carr. And the
22 question to you was: From the standpoint of arms and legs and
23 hooks, it's the same as the G2 and G2X?

24 And your answer is: It is very similar.

25 Now, did I read that correctly, sir?

1 A. Yes.

2 Q. Thank you.

3 MR. O'CONNOR: Felice, can we go to Exhibit 1616. Can
4 we orient that?

5 MR. LOPEZ: Give us a sec.

6 BY MR. O'CONNOR:

7 Q. Sir, it's sideways, but I'm showing you what is a G2 Filter
8 System Patient Questions and Answers.

9 Do you see that?

10 A. Yes.

11 Q. Now it's upside-down.

12 MR. LOPEZ: We're getting there.

13 BY MR. O'CONNOR:

14 Q. And this is a Bard document generated and produced by Bard?

15 A. If you show me the last page, please.

16 MR. O'CONNOR: All right. Last page, Felice.

17 THE WITNESS: Yes.

18 MR. O'CONNOR: I think -- all right. Thanks.

19 Felice, let's go to -- let's go back to the front.

20 Now, Felice, can you go to the page that ends in the last --

21 This is Exhibit 1616. Your Honor, I move to admit
22 1616 at this time.

23 MR. ROGERS: No objection, Your Honor.

24 THE COURT: Admitted.

25 (Exhibit No. 1616 admitted into evidence.)

1 MR. O'CONNOR: May I publish to the jury, Your Honor?

2 THE COURT: Yes.

3 MR. O'CONNOR: So, Felice, I would like to go to -- in
4 my notes, I have the last three digits of the Bates number 629,
5 so I think it may be exhibit page 6.

6 Thank you.

7 BY MR. O'CONNOR:

8 Q. And, sir, what Bard was advising people that ultimately
9 would use this filter is that the G2 filter is designed to be a
10 permanent implant and will not need to be removed,
11 repositioned, or replaced.

12 Did I read that correctly at the top, sir?

13 A. You did.

14 Q. Thank you.

15 And then going to the bottom, the question in the
16 question and answer for patients is: When can the filter be
17 removed? Is there a cutoff date by which the filter must be
18 removed?

19 Do you see where I'm reading, Mr. Carr?

20 A. Yes.

21 Q. And what Bard represented to people who may receive this
22 filter is the following: The G2 filter does not have a time
23 limit in which it must be removed. The filter can be removed
24 at any time after the point at which you no longer need it.
25 This is up to your physician.

1 Did I read that correctly, sir?

2 A. Yes.

3 MR. O'CONNOR: And, Felice, can you go to the third
4 page, the next page, which I think is 631 on the Bates number.

5 BY MR. O'CONNOR:

6 Q. And the last question: Does the filter have to be removed?

7 The answer is: No. The G2 filter is designed to be a
8 permanent implant and does not have to be removed,
9 repositioned, or replaced.

10 Did I read that correctly?

11 A. Yes.

12 MR. O'CONNOR: Felice, let's go to Exhibit 770,
13 please.

14 BY MR. O'CONNOR:

15 Q. Mr. Carr, this is a document entitled Denali Concept POA.

16 Do you recognize this document?

17 A. Yes.

18 MR. O'CONNOR: I move to admit into evidence, Your
19 Honor.

20 MR. ROGERS: And what exhibit number is that, please?

21 MR. O'CONNOR: 770.

22 MR. ROGERS: No objection, Your Honor.

23 THE COURT: Admitted.

24 (Exhibit No. 770 admitted into evidence.)

25 MR. O'CONNOR: May I display, Your Honor?

1 THE COURT: You may.

2 BY MR. O'CONNOR:

3 Q. And, Mr. Carr, the Denali POA was discussing a filter that
4 would also have caudal migration hooks, resistance; is that
5 correct?

6 A. I don't see it listed here, no.

7 Q. Is that your understanding, though?

8 A. No. There were multiple POAs.

9 Q. Okay. Is the Denali a filter that ultimately had caudal
10 anchors?

11 A. Yes, it does.

12 MR. O'CONNOR: Trying to find the section entitled
13 Unmet Needs in this document. Excuse me.

14 Felice, go to page 5.

15 BY MR. O'CONNOR:

16 Q. Sir, looking at a description of unmet needs and going to
17 the Problem section, let's talk about that for a moment,
18 please.

19 Now, the middle bullet point states the following:

20 The Bard G2 has a reported rate of 12 percent caudal migration,
21 18 percent tilt, and 22 percent penetration in the EVEREST
22 trial.

23 Did I read that correctly?

24 A. Yes.

25 Q. Thank you.

1 And below that section is a section called
2 Implications. And the implications of the current unmet needs
3 were, number one: The physicians who experience even one
4 challenging filter case may react strongly and choose to move
5 away from using the product altogether.

6 Did I read that correctly?

7 A. Yes, you did.

8 Q. And then another point that Bard made in the concept of the
9 Denali was the next one: Complications may drive physicians to
10 become more sensitive in patient usage of vena cava filter
11 therapy.

12 Did I read that correctly?

13 A. No, you didn't.

14 Q. Complications may drive physicians to become more selective
15 in patient usage of vena cava filter therapy.

16 Now did I read it correctly?

17 A. Yes.

18 Q. Thank you.

19 The next, based upon the implications of problems that
20 Bard stated in this document, is the following: Though
21 migration, tilt, and penetration are not seen as significant
22 issues, they have the potential to lead to more serious
23 problems.

24 Did I read that correctly?

25 A. Yes.

1 Q. And finally: A fractured arm or leg of a filter can result
2 in complications.

3 Did I read that correctly?

4 A. Yes.

5 Q. And so when you looked at the problems and the
6 implications -- the next section talks about the needs of a
7 filter. Let's go to that.

8 So at the time when you were developing the Denali
9 concept, Bard felt that a need for the filter had to be: A
10 filter that delivers performance characteristics of the current
11 design (example, effective clot trapping, long indwell time,
12 and accurate deployment), but with a higher resistance to
13 fracture, movement, and penetration.

14 Did I read that correctly?

15 A. Yes.

16 Q. And that would be a goal of the Denali filter; true?

17 A. Yes. We always look to improve our devices.

18 Q. But this is in connection with the Denali concept POA. Is
19 that right?

20 A. Yes. Which is a business document which describes the
21 intention of the project to be started.

22 Q. Thank you.

23 Now, sir, we talked about this a moment ago, but the
24 Recovery, G2, and G2X were permanent filters; correct?

25 A. They are all permanent filters with an option of removal,

1 yes.

2 Q. Those three filters were launched as permanent filters;
3 true?

4 A. The G2X was launched as an optional filter.

5 Q. Optional filters were permanent filters; true?

6 A. They are, yes.

7 Q. You agree that the G2 should perform as well as the Simon
8 Nitinol filter?

9 A. I don't believe it should perform as good in every
10 situation.

11 MR. O'CONNOR: Let's go to Mr. Carr's deposition dated
12 November 5, 2013.

13 And if you could, go to page 42.

14 (Conference off the record between Mr. O'Connor and
15 Ms. Wortman.)

16 MR. O'CONNOR: Pardon me? I think that's the one I
17 meant. I'm sorry. Oh, you don't have the November.

18 Well, then let's go to the transcript at 2162.

19 BY MR. O'CONNOR:

20 Q. All right. So at line 24, are you with me, Mr. Carr?

21 A. I see line 24, yes.

22 Q. You were asked: Now, sir, you agree that the G2 should
23 perform as well as the Simon Nitinol filter. True?

24 Let's go to the next page.

25 And then I said -- your answer was: No. I think it

1 performs differently in certain areas.

2 And then I said: All right.

3 And then we went to a deposition at that time; do you
4 remember? November 5, 2013, at page 42?

5 A. No, I don't. I'm sorry.

6 Q. Well, do you see the testimony there?

7 A. Yes.

8 Q. Okay. And that's what the testimony indicates; correct?

9 And my question to you was: And, Mr. Carr, I'm
10 looking down on page 42, line 14. You were asked: Would you
11 agree that they should perform as well as the Simon Nitinol
12 filter?

13 Let me put it in context. Do you see above where the
14 question that you were asked about the G2 and G2 Express at
15 line 5?

16 And I read that.

17 And within the context of what you just told me, would
18 you agree that the Recovery filter, the G2, and the G2 Express
19 should perform as well, if not better, than the Simon Nitinol
20 filter?

21 And your answer was: I don't know if they can perform
22 better.

23 Do you see where I read?

24 A. I do.

25 Q. And then the next question was: Would you agree that they

1 should perform as well as the Simon Nitinol filter?

2 And your answer was: Yes. They are substantially
3 equivalent.

4 Now, did I read that correctly?

5 A. You did.

6 Q. Thank you.

7 MR. O'CONNOR: Let's show Mr. Carr Exhibit 504.

8 BY MR. O'CONNOR:

9 Q. And, sir, you recognize this document?

10 A. Yes. Probably.

11 MR. O'CONNOR: Move to admit 504.

12 MR. ROGERS: No objection, Your Honor.

13 THE COURT: Admitted.

14 (Exhibit No. 504 admitted into evidence.)

15 MR. O'CONNOR: May we display to the jury, Your Honor?

16 THE COURT: You may.

17 BY MR. O'CONNOR:

18 Q. Mr. Carr, were you responsible for the development team,
19 the development of the Eclipse?

20 A. Not the entire time, no.

21 Q. But you were at some point in time; true?

22 A. Early, yes.

23 MR. O'CONNOR: Let's go to the Summary section,
24 Felice. Right at the top there.

1 BY MR. O'CONNOR:

2 Q. Now, this is the POA for the Eclipse anchor filter;
3 correct?

4 A. I don't know if it's the approved one, but it's the title
5 of the page, yes.

6 Q. Well, it's a Bard document; correct?

7 A. But if it's a draft, I don't know if it's a draft or not.

8 Q. Well, sir, my question is: Does this document say Bard in
9 the left-hand corner?

10 A. Oh, yes.

11 Q. And let's look at the Summary: This POA describes the
12 addition of anchors to the Eclipse filter.

13 Did I read that correctly?

14 A. Yes.

15 Q. And according to this POA, Bard had feedback from
16 customers.

17 Do you see where I'm reading, sir?

18 A. I do.

19 Q. And according to feedback from customers, the field and our
20 own clinical data have shown an increased frequency of
21 migration in the caudal direction with the G2 and the G2X
22 filters as compared to the Recovery.

23 Did I read that correctly, sir?

24 A. Yes.

25 Q. And it goes on to say that the idea between -- behind the

1 Eclipse anchor filter would be that the application of caudal
2 anchors would potentially eliminate this failure mode and
3 reduce tilting of the filter.

4 Did I read that correctly?

5 A. Yes.

6 Q. And the project would entail adding caudal anchors to the
7 Eclipse filter.

8 Did I read that correctly?

9 A. Yes.

10 Q. And continued use of the Eclipse filter delivery system
11 with some modifications.

12 Did I read that correctly?

13 A. Yes.

14 Q. Application of caudal anchors would potentially eliminate
15 the failure mode of caudal migration and reduce tilting of the
16 filter; is that correct?

17 A. That was our hope, yes.

18 MR. O'CONNOR: And let's go to Exhibit 769.

19 I believe this -- my notes indicate this is in
20 evidence, Your Honor.

21 THE COURTROOM DEPUTY: 769?

22 THE COURT: No. It's not.

23 BY MR. O'CONNOR:

24 Q. Mr. Carr, this is a Bard document entitled Meridian Claims
25 dated July 2, 2010.

1 Do you see that?

2 A. Yes, I do.

3 Q. And it has the words "Bard" meaning it is a Bard document;
4 true?

5 A. Not necessarily, but it has the word "Bard Peripheral
6 Vascular" at the top.

7 MR. O'CONNOR: I move to admit 769.

8 MR. ROGERS: No objection, Your Honor.

9 THE COURT: Admitted.

10 (Exhibit No. 769 admitted into evidence.)

11 MR. O'CONNOR: Felice, let's draw out --

12 Oh, may I publish Exhibit 69 [sic], please, Your
13 Honor?

14 THE COURT: Yes.

15 MR. O'CONNOR: And, Felice, could you enlarge that top
16 paragraph, "The purpose of"?

17 First of all, Felice, go up to the date July 10 -- 2,
18 2010.

19 BY MR. O'CONNOR:

20 Q. All right. So this document is dated July 2, 2010.

21 Do you see that, Mr. Carr?

22 A. I do.

23 Q. And it says: Please note that the claims listed are not
24 all intended to be incorporated into one sales brochure but
25 will be selectively used throughout different

1 promotional/educational materials.

2 Do you see where I read from?

3 A. Yes, I do.

4 Q. Thank you.

5 And did I read that correctly?

6 A. Yes.

7 MR. O'CONNOR: And in this document, Felice, if we
8 could go to Box F. And if you would enlarge that.

9 BY MR. O'CONNOR:

10 Q. And back in July of 2010, Bard said that the Meridian
11 filter is designed to resist caudal migration, decreasing the
12 likelihood of fracture to occur.

13 True? That's what it states?

14 A. No. This is an intended claim that we want to either prove
15 or disprove. It is a desire.

16 Q. Mr. Carr, did I read those words correctly?

17 A. You read the words correctly, but your question was not
18 correct.

19 Q. Let me state it differently.

20 What we're looking at states the following: The
21 Meridian IVC filter is designed to resist caudal migration,
22 decreasing the likelihood of fracture to occur.

23 Did I read those words correctly, sir?

24 A. Yes.

25 Q. Thank you.

1 And then in the parens, it says "Small print," colon.

2 Do you see where I'm referring to?

3 A. Yes.

4 Q. It states that based on clinical evidence from the EVEREST
5 trial, when migration and tilt are present, there is a higher
6 probability for fracture to occur.

7 Did I read those words correctly, Mr. Carr?

8 A. Yes.

9 Q. Thank you.

10 Those words I just read, were those words ever sent to
11 doctors in any type of brochure?

12 A. I don't know.

13 MR. O'CONNOR: I think that's all I have, Your Honor.

14 THE COURT: All right. Cross-examination.

15 MR. ROGERS: No questions at this time, Your Honor,
16 but we reserve the right to call Mr. Carr in Bard's case in
17 chief.

18 THE COURT: All right. You can step down, Mr. Carr.

19 (Witness excused.)

20 THE COURT: Unless you want to watch a video.

21 JURY MEMBER: They're really good.

22 THE COURT: Go ahead, Ms. Reed Zaic.

23 MS. REED ZAIC: Thank you, Your Honor.

24 The next witness will appear by videotape. His name
25 is Matt Fermanich, F-E-R-M-A-N-I-C-H. Matt Fermanich has a

1 bachelor's degree from the University of Wisconsin, Eau Claire.
2 He worked in pharmaceutical sales at Forest Pharmaceutical for
3 five years before joining Bard's sales force in 2009.

4 From 2009 to 2016, Fermanich was employed as a sales
5 representative in the Milwaukee, Wisconsin, area, servicing the
6 Wheaton Franciscan Hospital and Dr. David Henry, Lisa Hyde's
7 doctor. During this time, Fermanich reported to Tim Hug.

8 There are some exhibits to be moved into evidence.
9 Deposition Exhibit 3 will be trial Exhibit No. 4785; deposition
10 Exhibit 4 will be trial Exhibit No. 4786; deposition Exhibit 11
11 will be trial Exhibit 4794; deposition Exhibit 12 will be trial
12 Exhibit No. 4795; trial -- excuse me, deposition Exhibit 14
13 will be trial Exhibit No. 4797; deposition Exhibit 15 will be
14 trial Exhibit 4798; deposition Exhibit 21 will be trial Exhibit
15 No. 4804; deposition Exhibit No. 23 will be trial Exhibit 4806;
16 deposition Exhibit 26 will be trial Exhibit 4809; and
17 deposition Exhibit 29 will be trial Exhibit 4812.

18 I'd like to move all of these exhibits into evidence,
19 Your Honor.

20 MS. HELM: Your Honor, we don't have the script of
21 this -- of this deposition, so I'm operating at a bit of a
22 loss. We have the -- we have the objections to Exhibits 4804
23 and 4806 that have previously been discussed with the Court and
24 on which the Court has ruled. But I haven't seen the exhibits
25 as they're going to be played in the script to show that

1 they're properly redacted reflecting the Court's order.

2 MS. REED ZAIC: My understanding is that they have
3 been redacted in accordance with the Court's order since this
4 afternoon when we had a break.

5 THE COURT: All right. Assuming that redaction, is
6 there any objection?

7 MS. HELM: Actually, Your Honor, yes. We had a
8 previous representation that redactions had been made and they
9 weren't, and so we'd like to see the exhibits. And the script.

10 MS. SMITH: Your Honor, I can --

11 THE COURT: In the middle of the videotape, you'd like
12 to see?

13 MS. HELM: No, I'd like to see them now. I haven't
14 seen them. I'm sorry, I haven't seen the exhibits as redacted
15 or the script, so I'm operating in a little bit of a vacuum. I
16 apologize.

17 THE COURT: Well, I ruled on specific portions of the
18 script.

19 MS. HELM: And, Your Honor, two of the exhibits that
20 you ruled on previously are to be displayed in this transcript.

21 THE COURT: I know that. I'm just wondering how you
22 want to see it if it's in the video.

23 MS. SMITH: A script was provided to you. It's in
24 your email. And regarding the exhibits, we can print them out
25 to show you that they've been redacted, but I can assure you

1 they don't come up in the video.

2 And I can address the redactions that she was
3 discussing earlier --

4 THE COURT: Well --

5 MS. SMITH: -- after the jury is gone.

6 THE COURT: -- you redacted as I indicated?

7 MS. SMITH: Yes. They don't -- only the portion
8 that's been admitted will be showed.

9 THE COURT: Okay. With that understanding, do you
10 have an objection to the admission of any of these exhibits?

11 MS. HELM: No. Subject to your prior rulings, no,
12 Your Honor.

13 THE COURT: All right. Those exhibits are admitted.

14 (Exhibit Nos. 4785, 4786, 4794, 4795, 4797, 4798,
15 4809, and 4812 admitted into evidence.)

16 MS. HELM: Your Honor, may we be provided with a
17 script before the video is played?

18 THE COURT: What do you mean by a script?

19 MS. HELM: We exchanged -- it's the thing that you
20 ruled earlier, and so that we can follow and make -- because
21 it's not being taken down by the court reporter, so that we can
22 follow and make sure that the agreed-upon designations are
23 being played.

24 THE COURT: So what is it you want?

25 MS. HELM: I'm being told that -- I'm sorry. I'm

1 being talked to while I'm trying to listen to you.

2 I'm being told it's been sent to me. I don't see it.

3 I'm trying to look in my email.

4 THE COURT: What is it you want?

5 MS. HELM: A copy of it.

6 THE COURT: Of what?

7 MS. HELM: The script of the video that --

8 THE COURT: What do you mean, the script?

9 MS. HELM: Your Honor, again, it's the page/line
10 designations that are actually going to be played.

11 THE COURT: You just want page/line designations, or
12 do you want the actual testimony?

13 MS. HELM: The testimony.

14 THE COURT: You can follow along, right, in a
15 transcript?

16 MS. HELM: Yes, exactly, if I have it.

17 MS. SMITH: You have a copy right there, and it's only
18 those three that have been removed that was ruled on earlier,
19 and I sent you a copy.

20 Jim, did you receive it?

21 THE COURT: Well, I have a copy from earlier today
22 that has the four lines that I said should be removed, if you
23 want to follow along with that, Ms. Helm.

24 MS. HELM: Thank you, Your Honor.

25 THE COURT: All right. This will allow you to follow

1 along.

2 So I'm going to admit the exhibits that were moved
3 into evidence, subject to the redaction I had previously ruled
4 upon.

5 MS. REED ZAIC: Thank you.

6 I wanted to make a clarification just for Madam Court
7 Reporter. I believe that part of 4806 was already in evidence,
8 so there's no confusion.

9 THE COURT: Well, part of 4804 was too.

10 MS. REED ZAIC: I'm sorry. I meant to --

11 THE COURT: I made a more detailed ruling on 4804.

12 MS. REED ZAIC: Right.

13 THE COURT: Okay. Are you going to read an
14 introduction?

15 MS. REED ZAIC: I did, Your Honor.

16 THE COURT: Did you do that already?

17 MS. REED ZAIC: I did.

18 THE COURT: Okay. Let's go ahead and play the video
19 then.

20 (Video deposition played.)

21 THE COURT: Let's stop the video here.

22 All right, ladies and gentlemen. We will resume
23 tomorrow morning at 9:00 o'clock. Please remember not to
24 research the case or discuss it with anybody, and we'll see you
25 in the morning.

1 (Jury not present.)

2 THE COURT: Counsel, what is the time allocation for
3 the Ciavarella and the Fermanich depositions?

4 MS. HELM: Ciavarella, Your Honor, the plaintiff had
5 40 minutes, the defendants had 10 minutes.

6 For Mr. Fermanich, the plaintiff had 30 minutes, and
7 the defendants had 7 minutes.

8 THE COURT: Okay. Give me just a minute.

9 All right, counsel. As of this evening, plaintiffs
10 have used 20 hours and 50, 5-0, minutes. And defendants have
11 used 7 hours and 42 minutes.

12 And we'll plan to see you at 8:30 tomorrow morning.

13 MR. ROGERS: Thank you, Your Honor.

14 (Proceedings adjourned at 4:27 p.m.)

15

16

17

18

19

20

21

22

23

24

25

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am
duly appointed and qualified to act as Official Court Reporter
for the United States District Court for the District of
Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 26th day of
September, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC